

Application No.: 10/516,580
Filing Date: January 24, 2005

REMARKS

Claims 1-5, 19-21, and 32-39 are currently pending. New claims 38 and 39 refer to fermentation methods of specific dairy products. Support for claim 38 is found in the Specification as filed at claims 5, 20, and 21, and at page 12, lines 33-34; page 13, lines 27-30; page 14, lines 3-6, and page 31, Table 7. Support for claim 39 is found in the Specification as filed at claims 3, 5, 20 and 21, and at page 13, lines 27-30, and page 13, line 33-page 14, line 2. No new matter has been introduced herewith. The following addresses the substance of the Office Action.

Claim Objections

Claims 2 and 3 were objected to because both recite “an exopolysaccharide-producing lactic acid bacterial strain of Claim 1”. The claims are amended to recite “the exopolysaccharide-producing lactic acid bacterial strain of Claim 1”.

Enablement

The Examiner has rejected Claims 1-5, 19-21 and 32-35 under 35 USC §112, first paragraph, as being allegedly non-enabled. Specifically, the Examiner has requested filing an affidavit or declaration by applicants, assignees or a statement by an attorney of record stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application.

The deposit has been made under the terms of the Budapest Treaty and all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon grant of a patent on this application.

In light of the preceding statement, Claims 1-5, 19-21 and 32-35 are fully enabled, and their rejection under 35 USC §112, first paragraph should be withdrawn.

Indefiniteness

Claims 1-5, 19-21 and 32-35 were rejected as being indefinite. In particular, Claim 1 was held to be indefinite since the claim recited a strain “...encoding exopolysaccharide production.” It was unclear how a strain could encode exopolysaccharide production since only genetic

Application No.: 10/516,580
Filing Date: January 24, 2005

material can accomplish this. Thus, the claims are amended to recite a strain “...that produces exopolysaccharide.”

Claims 4 and 32 were considered indefinite by the recitation of “ 2.10^6 Dalton”. Claims 4 and 32 are amended to recite “ 2×10^6 Daltons”. In addition, similar amendments were made to withdrawn claims 8, 13, 25, 26, 27, 30 and 31.

Claim 19 was found to be indefinite due to the recitation “...adding the *Streptococcus thermophilus* ST 111 strain according to Claim 1 to the food fermentation process.” It was unclear how the strain was added to the food fermentation process, and there was no indication of where in the steps of the process the addition of the strain takes place. Claim 19 is amended to recite “...adding a functional starter culture or coculture of the *Streptococcus thermophilus* ST 111 strain according to claim 1 to said food at the start or during the food fermentation process. Thus the amended claim specifies how and when the *Streptococcus thermophilus* ST 111 strain is added. Support for the amendment is found in the Specification as filed on page 2, lines 25-28 and page 3, lines 26-29.

In light of the claim amendments and the preceding remarks, removal of the indefiniteness rejections under 35 U.S.C. § 112, second paragraph is respectfully requested.

Anticipation

Claims 1, 2, 4, 5, and 19-21 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lemoine et al. (US 5,965,127) or Faber et al. 1998 *Carbohydrate Research* **310**:269-276.

Lemoine et al. discloses a *Streptococcus thermophilus* CNCM I-1878 strain producing exo-polysaccharides, whereby the EPS essentially consist of D-galactose, L-rhamnose and D-glucose in a molar ratio of 3:2:1 (see column 2, lines 20-21). The EPS are eluted at an exclusion limit of approximately 2×10^6 daltons, and thus inherently have to our understanding a MW of at least 2×10^6 daltons. The strain is said to be grown in skim milk powder reconstituted at 10% (see column 3, lines 56-58).

Faber et al. disclose two *Streptococcus thermophilus* strains St and Rs which produce heteropolysaccharides having a molecular-mass of at least 2×10^6 daltons. Faber et al. also disclose milk cultures of the *Streptococcus thermophilus* strains and use of *Streptococcus thermophilus* in combination with lactic acid bacteria as yoghurt starters. The Applicants note

Application No.: 10/516,580
Filing Date: January 24, 2005

that the strains are said to have EPS which contain galactose and rhamnose in a molar ratio of 5:2, which is believed to be similar to the EPS of the present application.

The examiner acknowledges that Faber et al. and Lemoine et al. do not specify the strain disclosed in the present application, which is deposited under accession number LMG P-21524. However, the examiner considers that the strains disclosed in Faber et al. and Lemoine et al. appear to be identical with the present strain since they belong to the same species and produce heteropolysaccharide having molecular weight of at least 2×10^6 daltons. The Applicant respectfully disagrees with that presumption.

The Applicants emphasize that the presently claimed strain deposited under accession number LMG P-21524 is different from the strains disclosed in Faber and Lemoine. It is true that the strains disclosed in Faber et al. and Lemoine et al. are of the same species as the claimed strain and they produce heteropolysaccharide of molecular weight that is at least 2×10^6 daltons. Faber et al. even discloses two *Streptococcus thermophilus* strains, Rs and St that are of the same species and produce a heteropolysaccharide of molecular weight of at least 2×10^6 daltons. However, different strains can have other properties that are divergent. For example, the two strains disclosed by Faber et al. are very different from each other as stated in the abstract and on page 270, left column, 3rd paragraph: “*S. thermophilus* Rs and St strains were selected on the basis of huge differences in viscosifying properties of their milk cultures” (emphasis added). Thus, Faber et al. recognizes that different strains of the same species of *Streptococcus thermophilus* can be quite different from each other even if they share the property of producing a heteropolysaccharide having a molecular weight of at least 2×10^6 daltons. Moreover, the strains disclosed in Faber et al. and Lemoine et al. are not identical even though both references disclose that the strains belong to the same species and produce heteropolysaccharides with molecular weight of at least 2×10^6 daltons. Thus, the Examiner’s conclusion that bacteria belonging to the same species and producing heteropolysaccharide having a molecular weight of at least 2×10^6 daltons are the same is incorrect.

Secondly, the applicants note that the *Streptococcus thermophilus* ST111 strain is distinct, and therefore novel, from the *Streptococcus thermophilus* Sts and Rs strains disclosed by Faber et al. (1998) because it has a different origin. ST111 was isolated from an artisan Romanian dairy product (see page 4, lines 28-30 of the Specification as filed), whereas strains St

and Rs originated from the Netherlands (see Faber et al., page 274, left column, first paragraph under the header “Experimental”). Given that variation between strains arises locally (e.g., “huge differences” between St and. Rs strains) and that the source of the strain of the present application is quite remote from the sources of the strains in the cited prior art, it is highly improbable that they are the same.

The applicants note that the EPS produced by different strains do not necessarily have identical repeating units and/or the same distribution of molecular weights. For example, the repeating unit disclosed by Lemoine et al. as illustrated at column 5, 2nd full paragraph is different from the repeating unit disclosed in the present application illustrated at page 9, lines 14-19 of the Specification as filed. The repeat structure illustrated by Lemoine et al. has a non-reducing terminal β-Galp (F) residue, while the repeating unit disclosed in the present application does not have such a terminal sugar residue at the analogous position. Thus, strain-specific differences may affect the sequence of sugar residues, the degree of branching, or the types of linkages between the sugar residues in the heteropolysaccharide.

In view of the above remarks, the subject of claim 1 and dependent claims thereof are not anticipated and removal of the rejection is respectfully requested.

Obviousness

Claims 1, 2, 4, 5, and 19-21 were rejected in the alternative under 35 U.S.C. § 103(a), as obvious over Lemoine et al. (US 5,965,127) or Faber et al. 1998 *Carbohydrate Research* 310:269-276. However, the Applicants point out that the exopolysaccharide (EPS) obtained by the present invention having a high molecular mass is very stable. The stability is referred to throughout the Specification as filed, for example in the title of the application, at page 1, line 6; page 5, line 18; and page 8, line 33-page 9, line 5; and Figure 5, which shows a distinct peak of the pure EPS with negligible or no degradation into lower molecular mass products.

Streptococcus thermophilus ST 111 produces a high molecular weight EPS that is exceptionally stable over time. Referring to page 8, lines 33-35, the monomer composition of the high molecular mass exopolysaccharide produced by *S. thermophilus* ST 111 is not influenced by the physical growth conditions, such as pH of medium and temperature. Moreover, there is no or negligible degradation into lower molecular mass products over time. Thus, it is possible to

Application No.: 10/516,580
Filing Date: January 24, 2005

produce better yoghurts, having a better consistency (higher viscosity) with little or no synerese (water releasing) activity.

The exceptional stability of the exopolysaccharide produced by *S. thermophilus* ST 111 is an unexpected result since there is no suggestion, let alone teaching in Faber et al. and Lemoine et al., that stable, high molecular mass EPS is obtained by *Streptococcus thermophilus* strains. Neither Faber et al. nor Lemoine et al. recognized the problem in the prior art that the amounts of EPS produced by lactic acid bacteria were low and their production was unstable. Thus, the cited references do not provide any reason to search for additional strain(s) capable of producing exopolysaccharide that have the exceptional stability observed with *S. thermophilus* ST 111.

Claims 1-5, 19-21 and 32-35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lemoine et al. or Faber et al. in view of Cravero (US 6,033,691). Lemoine et al. and Faber et al. do not expressly disclose a co-culture comprising the exopolysaccharide producing strain, but Cravero discloses a method for the preparation of a biologically active milk product using a co-culture of Lactobacillus strains and a *Streptococcus thermophilus* strain. In Cravero et al., the *Streptococcus* strain is added for its proteolytic activity, which is absent or lower for Lactobacillus strains (see column 7, lines 56-59).

For the same reasons discussed above, (*i.e.*, the unexpected and exceptional stability of the exopolysaccharide produced by *S. thermophilus* ST 111), the claims are not obvious in view of the cited references. The cited references do not provide any reason to search for additional strain(s) capable of producing exopolysaccharide that have the exceptional stability observed with *S. thermophilus* ST 111. Thus, the claims are not obvious in light of the cited references and removal of the rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present

Application No.: 10/516,580
Filing Date: January 24, 2005

disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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